RISK ASSESSMENT FOR FOODBORNE ILLNESS

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Risk assessment is a systematic process of understanding factors that influence the risk of adverse events such as the occurrence of foodborne illness. Some risk assessments may involve many assumptions, few data and much "expert opinion". The latter subjective inputs may not necessarily be evidence- or science-based and thus the entire assessment may be associated with great uncertainty and be considered by some not to be science. This is not the fault of the risk assessor but often reflects a pressing political or societal need for a risk assessment before adequate information and/or empirical data are available. Regardless of this limitation, a risk assessment of foodborne illness can often define important questions and data gaps that warrant future research. In addition, it is important to note that depending on the specific question that is being addressed, risk assessments might need to only be qualitative or semi-quantitative, rather than completely quantitative. In a quantitative risk assessment, a numeric estimate of risk is obtained and the uncertainty in the estimate is specified. Epidemiologic methods and tools are central to the risk assessment process.

The risk assessment process has 4 main stages: hazard identification, exposure assessment, hazard characterization and risk characterization (see Appendix for definitions). Essentially, the process attempts to answer the following questions:

- What can go wrong?
- How likely is the event to occur?
- What are the consequences if the hazard occurs?

The risk assessment process (although separate from risk management) may involve evaluation of interventions or strategies to mitigate the risk of illness. In contrast, risk management focuses on decisions and policy, and considers issues of risk as well as human and societal values and judgements. Risk management concepts will be described in detail in the next presentation but it is clear that risk assessment can greatly contribute to the decision-making process. Use of a standardized and transparent risk assessment procedure should also facilitate risk communication to stakeholders.

Risk assessment can provide useful information for developing and refining Hazard Analysis and Critical Control Point (HACCP) programs for food producing industries but I will not elaborate on this relationship here. In the limited time available, I will provide my perspective, as a veterinary epidemiologist, of important issues in the context of risk assessment and foodborne illness, and indicate some of the research needs and studies that will facilitate sound risk assessments. I will use an example of *Escherichia coli* O157 in feedlot cattle to demonstrate the type of prospective longitudinal studies that are needed to integrate animal data from the farm and carcass-level data through the slaughter processing system. I will not focus on public health aspects, but indicate that there are critical research needs in areas such as characterization of individual- and population susceptibility to microbial pathogens in human subpopulations such as the elderly and immunocompromised.

RISK ASSESSMENT - WHERE ARE WE NOW?

In the last 5 years, there has been substantial progress in developing systematic general approaches for quantitative risk assessments for microbes in food products and their production processes. Much of this work is published in journals such as the International Journal of Food Microbiology, Journal of Food Protection and the Journal of Applied Microbiology and therefore it is reasonable to say that it is scientifically recognized. These general approaches have been adapted for specific microbial hazards including assessments of:

- *Listeria monocytogenes* in soft cheese
- *Salmonella enteritidis* in pasteurized liquid eggs and Salmonella sp. in chicken products
- *E. coli* 0157: H7 in ground beef hamburger

In addition, there has been substantial research progress on a variety of topics including:

- Modeling the uncertainty and variability in data through probability distributions
- Modeling the uncertainty that is attributable to the predictive microbial growth model
- Choosing the "best" statistical model for microbial growth
- Extrapolation of data to low-dose exposures.

Although there are areas of modeling that require further development, I don't believe that this is the major limiting factor in risk assessment. As an epidemiologist it is clear to me that the greatest limitation is the lack of valid empirical data to fill many gaps in our risk assessment models. For example, if you read the current draft assessment of the "Relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods", 12 of 13 points in the section on information and research needs make reference to data and studies.

It is also important to note that most of the existing risk assessment models are unvalidated i.e. even if they were constructed on the basis of empirical data, they have not been validated under naturally-occurring conditions. Furthermore, most of the empirical data used in these models were derived from limited observations or experiments. We really don't know whether the models are correct, partially correct, or even somewhat reflective of the truth. However, the old adage "all models are wrong but some models are useful" probably applies because it is clear that they identify some of the critical information and research needs. Furthermore, models can always be updated in an iterative way, as the data become available.

RISK ASSESSMENT – WHAT DO WE NEED IN THE FUTURE?

Clearly, there is a pressing need to design and implement well-designed descriptive and risk-factor studies that will fill data gaps in a timely fashion. Ideally, these studies should link the farm, the slaughter process and post process handling of carcasses and meat/food products. Historically, studies have focussed on one part of the process rather than taking a more integrative approach. Data from longitudinal studies has great potential for facilitating the role of risk assessors and ultimately providing better data for decision-makers.

There are a number of logistical and technical challenges that make this less than straightforward. Amongst these are that some pathogens such as *L. monocytogenes* are found in multiple animal species and multiple ready-to-eat foods. Furthermore, there are multiple strains of the organism. The feasibility of longitudinal studies is much greater for pathogens such as *E. coli* 0157:H7 that essentially have a single animal host and most human outbreaks involve one food type i.e. raw or undercooked hamburger.

However, a systematic evaluation of one or two specific food items e.g. fresh soft cheese and deli meats and one or two strains of *L. monocytogenes* might have greater long-run benefits than a more general approach to foodborne listeriosis.

I will mention some technical issues that apply to studies of all foodborne pathogens:

- Collection of data in live animals or at the slaughter plant involves diagnostic tests that are imperfectly sensitive and specific. For example, if 10 of 100 (10%) of samples are culture-positive for Salmonella, what is the true prevalence of *Salmonella* infection? Is the true prevalence of infection 15%, 20% or another value? We can only adequately address this question with an estimate of the field performance characteristics of the tests, especially the many rapid tests that are currently available or under development.

- Prevalence data are often presented and used in a summary form that ignores the fact that animals are spatially aggregated and that not all pathogens are present in animal populations at the same frequency. This latter phenomenon is reflected in a range of values among farms i.e. some farms have a low prevalence of infection, others have a moderate prevalence of infection and others a high prevalence of infection. Such data are practically useful because they can form the basis of on-farm control programs and mitigations at slaughter plants e.g. Salmonella control program in Danish swine herds.

- Most of the prevalence data for microbial pathogens in food products are qualitative (yes/no) and the level of contamination has not been quantified.

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- Optimal sampling approaches to deal with clustering of pathogens in live animals and carcasses require development and validation for many pathogens.

INTEGRATED "FARM TO PRODUCT" STUDIES: AN EXAMPLE

I would like to provide an overview of an example study that I believe is the type of collaborative effort that is necessary to tackle many of these complex food safety research needs. I use this example as one of the many solutions/approaches to provide critical epidemiologic data that are needed to fill data gaps in risk assessments.

E. coli O157: H7 is ubiquitous in U.S cattle feedlots but pen prevalence within feedlots is highly variable (0 to 70%). Risk factors associated with higher prevalence as evidenced by fecal shedding of the organism include wetter condition of the pen floor, lower body weights at entry to the feedlot, time on feed, type of ration and season of the year when sampled. At the slaughter plant, practices that lead to lower frequencies of carcass contamination with *E. coli*, in general, have been documented and mitigation strategies evaluated. However, there is no research that has evaluated carcass contamination relative to the shedding of *E. coli* O157 in live animals by testing cattle preshipment and at various stages of processing in slaughter plant. A key research question is whether "pen-risk" of *E. coli* O157, as evaluated by diagnostic tests immediately preshipment, is correlated with carcass risk of *E. coli* O157.

The widely variable prevalence among animals and pens suggests a basis for variability in the risk of contamination of carcasses and therefore variability in risk of contamination of meat products destined for human consumption. In order to accurately predict the risk of carcass contamination most closely, evaluation of the level of shedding in pens of cattle immediately prior to shipment to slaughter would be of the most practical use in allowing intervention strategies to be implemented based on the level of risk. These interventions could include processing cattle from high-risk pens at the end of the day's kill to

minimize the risk of contamination to animals in low-risk pens and the selective use of acid washes of the carcass.

We have set up a multidisciplinary and multi-institutional team of epidemiologists, animal scientists, laboratory diagnosticians, statisticians and biologists who are proposing to investigate the problem. The proposed project involves collaboration between universities, government agencies, livestock producers and slaughter plants. Colorado State University and University of California, Davis are the academic institutions involved but collaborating partners include the Food Safety and Inspection Service (FSIS), the Animal Plant Health Inspection Service: Centers for Epidemiology and Animal Health and the Rocky Mountain Regional Animal Health Laboratory. The American Meat Institute Foundation has indicated strong support for the proposal.

CONCLUSIONS

Risk assessment should not be viewed as a panacea for reducing food-borne illness. The process of doing a risk assessment, however, even if based primarily on expert opinion can be useful for identifying critical data and research needs. Once these needs are identified, they need to be prioritized and resources allocated to address them. However, there are numerous challenges in determining how best to objectively rank all data needs for all the foodborne pathogens.

More scientifically-rigorous studies are needed to provide the necessary data for sound risk assessments. There is a pressing need for field studies that essentially have a "farm to product" approach and include the evaluation of mitigation strategies. Optimal testing and sampling strategies need to be developed for each of the foodborne pathogens so that cost-effective but epidemiologically-valuable surveillance systems can be implemented. In addition, there is a need to analyze existing surveillance data from agencies such as FSIS and critically evaluate its value to the risk assessment process.

Now is the time to forge solid multidisciplinary partnerships between university researchers, government agencies and food-producing groups to tackle many of the difficult questions and bridge data gaps.

APPENDIX

Definitions and terms related to the risk assessment process:

Hazard identification – the identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods

Hazard characterization – the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents that may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Exposure assessment – the qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures to other sources, if relevant.

Risk characterization - the qualitative and/or quantitative estimation, including the uncertainty in that estimate, of the probability and severity of known or potential adverse effects in a given population, based on hazard identification, hazard characterization and exposure assessment.